

(d) Once a depository is recognized to be suitable by the Director or has defaulted or discontinued its performance under this section, notice thereof will be published in the Office Gazette of the Patent and Trademark Office.

§ 1.804 Time of making an original deposit.

(a) Whenever a biological material is specifically identified in an application for patent as filed, an original deposit thereof may be made at any time before filing the application for patent or, subject to § 1.809, during pendency of the application for patent.

(b) When the original deposit is made after the effective filing date of an application for patent, the applicant must promptly submit a statement from a person in a position to corroborate the fact, stating that the biological material which is deposited is a biological material specifically identified in the application as filed.

[54 FR 34880, Aug. 22, 1989, as amended at 62 FR 53202, Oct. 10, 1997]

§ 1.805 Replacement or supplement of deposit.

(a) A depositor, after receiving notice during the pendency of an application for patent, application for reissue patent or reexamination proceeding, that the depository possessing a deposit either cannot furnish samples thereof or can furnish samples thereof but the deposit has become contaminated or has lost its capability to function as described in the specification, shall notify the Office in writing, in each application for patent or patent affected. In such a case, or where the Office otherwise learns, during the pendency of an application for patent, application for reissue patent or reexamination proceeding, that the depository possessing a deposit either cannot furnish samples thereof or can furnish samples thereof but the deposit has become contaminated or has lost its capability to function as described in the specification, the need for making a replacement or supplemental deposit will be governed by the same considerations governing the need for making an original deposit under the provisions set forth in § 1.802(b). A replacement or supplemental deposit made during the pend-

ency of an application for patent shall not be accepted unless it meets the requirements for making an original deposit under these regulations, including the requirement set forth under § 1.804(b). A replacement or supplemental deposit made in connection with a patent, whether or not made during the pendency of an application for reissue patent or a reexamination proceeding or both, shall not be accepted unless a certificate of correction under § 1.323 is requested by the patent owner which meets the terms of paragraphs (b) and (c) of this section.

(b) A request for certificate of correction under this section shall not be granted unless the certificate identifies:

- (1) The accession number for the replacement or supplemental deposit;
- (2) The date of the deposit; and
- (3) The name and address of the depository.

(c) A request for a certificate of correction under this section shall not be granted unless the request is made promptly after the replacement or supplemental deposit has been made and the request:

- (1) Includes a statement of the reason for making the replacement or supplemental deposit;
- (2) Includes a statement from a person in a position to corroborate the fact, and stating that the replacement or supplemental deposit is of a biological material which is identical to that originally deposited;
- (3) Includes a showing that the patent owner acted diligently—
 - (i) In the case of a replacement deposit, in making the deposit after receiving notice that samples could no longer be furnished from an earlier deposit; or
 - (ii) In the case of a supplemental deposit, in making the deposit after receiving notice that the earlier deposit had become contaminated or had lost its capability to function as described in the specification;
- (4) Includes a statement that the term of the replacement or supplemental deposit expires no earlier than the term of the deposit being replaced or supplemented; and
- (5) Otherwise establishes compliance with these regulations.